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| 10/572,968 | 03/21/2006 | Kenneth Alan Simmen | TIP-0054-USPCT | 4586 |
| 27777 7590 11/25/2008 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | | |
| EXAMINER | | | | |
| RAO, SAVITHA M | | | | |
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| 11/25/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/572,968

Applicant(s)

SIMMEN ET AL.

Examiner

SAVITHA RAO

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
- Paper No(s)/Mail Date 03/21/2008
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 12 is pending and is the subject of this office action

Election/Restrictions

Applicant's election without traverse of Group I (originally claims 1-14), directed to sulfonamide compounds, in the reply filed on 10/17/2008 is acknowledged.

Applicant has cancelled claims 1-11 and 13-16 and has limited pending claim 12 to a single compound, which obviates the requirement for election of a single species of sulfonamide compound.

Amended claim 12 is directed to the elected subject matter and will be examined in this office action.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical

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name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

In the instant case, Claim 12 recites a genus of "N-oxides". As evidenced by Bickel (The pharmacology and Biochemistry of N-Oxides, Pharmacological reviews, Vol 21, 325-355, 1969, abstract), N-oxides are oxidation products of tertiary amines. Bickel discloses that in several cases N-oxides are more active than their corresponding tertiary amines. Additionally Bickel teaches that N-oxides play an important role in the metabolism of drugs. Accordingly, N-oxide derivatives of the originally claimed compound in instant claim 12 would be reasonably expected to have different chemical and physical properties and may elicit biological activity different from the original compound. The instant disclosure does not provide sufficient evidence for "N-oxides "as claimed in the instant disclosure in terms of a chemical structure.

Accordingly, for an ordinarily skilled artisan to test N-oxides of the claimed compounds would impose undue burden.. "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing

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distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention." Please see MPEP § 2163. Applicants are imposing the burden of extensive testing upon the skilled artisan to identify the N-oxide derivatives that may or may not have any of the disclosed functions, but which Applicants have not identified and thus, were not in possession of, at the time of the present invention. It has been held in patent law that a wish or plan for obtaining the invention as claimed does not provide adequate written description of a chemical invention. Rather, a precise definition, such as by structure, formula, chemical name or physical properties or a combination thereof, is required. Please reference, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004). In other words, though Applicants may have a plan for how to identify other agents that may be amenable for use in the present invention, it remains that at the time of the invention Applicants had not identified such compounds, and, therefore, did not have written description of "N-oxides" claimed.

Claim Rejections - 35 USC § 102(a) and 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed

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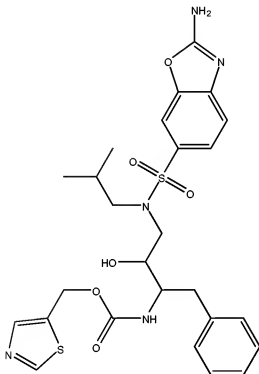
before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(c) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 12 is rejected under 35 U.S.C. 102(e) and alternatively under 35 U.S.C. 102 (a) as being anticipated by Surleraux et al (WO 02/081478).

Instant claim 12 recites the following compound for inhibiting HCV activity in a subject.

{ 3-[(2-Amino-benzoxazole-6-sulfonyl)-isobutyl-amino]-1-benzyl-2-hydroxy-propyl}-carbamic acid thiazol-5-ylmethyl ester;

Which is structurally represented as follows (structure generated in ChemDraw)

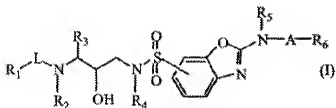


The recitation of the intended use utility of the instantly claimed compound for inhibiting HCV activity in a subject are intended uses of the compound and will be given little patentability weight in the

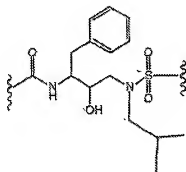
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absence of a showing that such claimed intended uses result in a material difference in the claimed compositions.

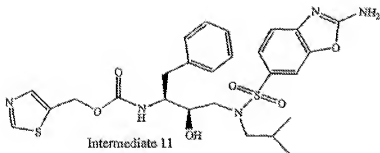
Surleraux discloses broad-spectrum 2-(substituted-Amino)-Benzoxazole Sulfonamide HIV Protease inhibitors of the general formula (I) (abstract) shown below



Surleraux further discloses that compounds of the following core structures act as retroviral protease inhibitors (page 2, line 34- page 3, line 2)



Surleraux additionally discloses Intermediate 11 useful in the synthesis of his compound 10 as having the following structure (page 35, lines 10-15)



The instantly claimed compound is therefore entirely anticipated by intermediate 11 of Surleraux. Additionally, since Surleraux teaches that the core structure imparts a protease inhibitory activity, the intermediate 11 of his teachings and the instantly claimed compounds would have been reasonably expected to also be useful in the inhibition of HCV protease.

Accordingly, Surleraux anticipates the agent claimed in instant claim 12

Conclusion

Claim 12 is rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614